



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bulk Manufacturer of Controlled Substances Application: Halo Pharmaceutical, Inc.

[Docket No. DEA-392]

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrisette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than

final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on July 24, 2015, Halo Pharmaceutical, Inc., 30 North Jefferson Road, Whippany, New Jersey 07981 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

<u>Controlled Substance</u>	<u>Schedule</u>
Dihydromorphine (9145)	I
Hydromorphone (9150)	II

The company plans to manufacture Hydromorphone HCl for sale to other manufacturers and to manufacture other controlled substances for distribution to its customers. Dihydromorphine is an intermediate in the manufacture of Hydromorphone and is not for commercial distribution.

Dated: October 13, 2015

Louis J. Milione,
Deputy Assistant Administrator.

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